THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,	:	
	:	
Plaintiff,	:	
	:	Civil Action No.
v.	:	
	:	Jury Trial Demanded
ERNST & YOUNG, LLP	:	
	:	
Defendant.	:	

COMPLAINT

Plaintiff, United States of America, for its Complaint against Defendant Ernst & Young, LLP ("Ernst & Young") alleges:

1. This action seeks damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-33, as amended, and the common law theories of payment by mistake and unjust enrichment as a result of causing the submission of over two hundred thousand claims for payment for outpatient clinical laboratory tests billed to the Medicare Program ("Medicare") for the period 1991 through and including 1997. This is an action by the United States to recover over nine hundred thousand dollars ($900,000) in laboratory payments improperly claimed and received by nine hospital providers (who were clients of Ernst & Young) (the "nine hospitals") from the Medicare program to which they were not entitled.

Ernst & Young held itself out to clients and potential clients as having substantial expertise in hospital reimbursement matters. Each of the nine hospitals had retained Ernst & Young during the period from 1991 through 1995, and paid for billing advice that caused the submission of false claims for laboratory services. The advice was based upon the results of analyses performed by Ernst & Young for two types of reviews: 1) a Charge Description Master

Review ("CDM"), which was performed for four of the client hospitals; or 2) an outpatient laboratory review specifically related to the ongoing investigation in the case filed against Harry J. Metzinger, et al (the " Metzinger investigation"). As a result of the Metzinger investigation, five of the client hospitals were notified that they were potentially in violation of governing reimbursement law and regulation. Each of these Hospitals hired Ernst & Young to perform an independent review, as requested by the United States Attorney's Office ("USAO"). Certain of the reports submitted by Ernst & Young were misleading as to the extent of improper billing and submission of claims to the Medicare Program, and failed to disclose the extent of improper billing by the hospital, or Ernst & Young's role in causing improper billing.

THE PARTIES

2. Plaintiff is the United States of America ("United States") acting for the United States Department of Health and Human Services ("HHS") and the Medicare Trust Fund.

3. The Defendant, Ernst & Young, is a national CPA firm providing consulting and certified public accounting services, with offices throughout the United States and various foreign countries. It claims expertise in the "key industry area" of healthcare. At all times relevant, Ernst & Young transacted business within the Eastern District of Pennsylvania and is subject to the personal jurisdiction of this Court.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1345, since the United States is plaintiff, and 31 U.S.C. § 3732.

5. Venue is proper in the Eastern District of Pennsylvania pursuant to 31 U.S.C. § 3732 and 28 U.S.C. § 1391 because Ernst & Young transacted business in this district. As professional advisors, representatives of Ernst & Young made submissions to the United States in this district, visited this district, made telephone calls into the district, and/or sent letters to this district.

THE MEDICARE PROGRAM

6. Medicare is a federal program created by the Social Security Act, as amended, 42 U.S.C. § 301 *et seq*., which provides health insurance for individuals aged at least 65 years and to certain disabled persons under the age of 65. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS")[1] and funded through HHS.

7. Medicare includes coverage under two components: hospital insurance (Part A); and medical insurance (Part B). Coverage under Part B includes services rendered by doctors, outpatient hospital care and other medical services not covered by Part A. The Part B program is funded by premiums paid by Medicare beneficiaries enrolled in the program and is supplemented by contributions from funds provided and paid by the United States. Hospital claims for payment for Part B services, including diagnostic laboratory tests provided to Medicare beneficiaries, are processed by fiscal intermediaries. 42 U.S.C. § 1395h(a); 42 C.F.R. § 421.5(c). Each hospital provider is assigned a specific fiscal intermediary to process that provider's claims. During the time period from 1990 to the present, the fiscal intermediaries varied as to who had contracts with CMS to process and pay Part B claims.

[1]Prior to June 14, 2001, the Centers for Medicare and Medicaid Services was named the Health Care Financing Administration ("HCFA").

For instance, Mutual of Omaha Insurance Company ("Mutual of Omaha"), located in Omaha, Nebraska, is currently one of the fiscal intermediaries for this district. In June of 1997, Mutual of Omaha took over the administration of Medicare claims from Aetna Life Insurance, located in Fort Washington, Pennsylvania, which was the fiscal intermediary for several hospital providers during the period from 1991 through 1997. Other fiscal intermediaries who processed claims for Medicare during this time period include: Veritus, Inc. ("Veritus"), located in Pittsburgh, Pennsylvania; AdminaStar Federal ("AdminaStar"), located in Indianapolis, Indiana; and United Government Services (formerly known as Blue Cross Blue Shield of Virginia or Trigon.)

8. The Part B Program pays claims for reimbursement submitted by or on behalf of Medicare beneficiaries for a portion of the reasonable charges of certain medical services, including certain outpatient clinical laboratory services, which are determined to be reasonable and necessary under §§ 1861(s) and 1842(a)(1) of the Social Security Act, 42 U.S.C. §§ 1395x(s) and 1395u (a)(1). CMS determines the types of services covered and therefore reimbursable based upon medical necessity and the amount to be paid based upon a fee schedule.

9. Medicare assigns provider numbers to health care providers. The use of these provider numbers allows the health care providers to bill the fiscal intermediary or carrier directly for services rendered to patients who are eligible to receive medical services under the Part B Program.

10. In order to be paid for services rendered or supplies provided, a hospital provider that participates in the Medicare Part B Program submits claims for payment to the

fiscal intermediary via either: (a) a hard copy "Request for Medicare Payment" form (Form HCFA 1450); or (b) an electronic submission.

11. A claim for outpatient laboratory tests identifies the name of the Medicare beneficiary, the name of the ordering physician, the date the service was provided, the CPT codes (defined below in paragraph 13) of the tests performed, and at certain times the ICD-9 number (diagnosis code) corresponding to the medical condition for which the test is needed.

12. Each outpatient laboratory test billed by a hospital to Medicare must be ordered in writing by a treating physician with a valid license, be medically necessary in the view of the treating physician for diagnosis or treatment of the patient's condition, be actually performed, and have the results of the tests recorded in laboratory records and reported to the treating physician. Hospital records must exist and be maintained to support each of the requirements set forth in this paragraph, but the records need not be provided to the Medicare intermediary unless specifically requested.

13. Health care providers for all federal health care benefit programs, including Medicare, use a uniform system of coding to report professional services, procedures, supplies and diagnoses. Medical services are assigned a number and are listed in certain publications. The HCPCS system is a three-level system of coding developed by the then HCFA. "HCPCS" is the acronym that stands for Health Care Finance Administration Common Procedure Coding System. Level I of the HCPCS coding system is the American Medical Associations's Physician's Current Procedural Terminology ("CPT") Codes. CPT codes are five-digit codes with descriptive terms for reporting services performed by health care providers. Outpatient clinical laboratory procedures are assigned a procedure code and are

listed in the CPT codes. Fiscal intermediaries and providers often refer to CPT codes and HCPCS codes generally as HCPCS codes.

14. The Medicare claim submitted by health care providers is the invoice relied upon by Medicare to pay providers, including the nine hospitals who were clients of Ernst & Young.

15. At all times relevant to this complaint, the nine hospitals were participating Medicare providers.

16. At all times relevant to this complaint, Ernst & Young was aware that Medicare relied initially on the provider's claims to authorize payment of Medicare funds for laboratory services.

NATURE OF THE FALSE OR FRAUDULENT CLAIMS

17. During the period of 1991 through 1997, the nine hospital clients either operated clinical laboratories or contracted with outpatient clinical laboratories that, among other things, performed certain blood tests on Medicare beneficiaries. Ernst & Young caused the nine hospitals to submit claims during the period from 1991 through 1997 which reflect the billing of certain blood tests which were performed, and not medically necessary.

Blood Tests

18. Blood tests or hematology tests include blood cell counts which are used to evaluate and diagnose disease relating to abnormalities of the blood or bone marrow. These include primary disorders such as anemia, leukemia, polycythemia, thrombocytosis and thrombocytopenia. Single CPT codes exist for individual components of blood counts as well as for common combinations of such tests. When a combination of hematology tests is performed

on an automated basis, they are often referred to as a complete blood count ("CBC"). A CBC may include such component tests as a hematocrit, hemoglobin, red and white blood cell counts, platelet count, differential white blood cell counts (manual or automated) and a number of standard indices. When there is a combination code that describes the tests performed, then that code must be used rather than billing multiple separate codes. The blood count tests, and their respective HCPCS codes, are described as follows:

HCPCS 85021	Blood count; hemogram, automated (RBC, WBC, Hgb, Hct, and indices only)
HCPCS 85022	Blood count; hemogram, automated, and manual differential WBC count (CBC)
HCPCS 85023	Blood count; hemogram and platelet count, automated, and manual differential WBC count (CBC)
HCPCS 85024	Blood count; hemogram and platelet count, automated, and automated partial differential WBC count (CBC)
HCPCS 85025	Blood count; hemogram and platelet count, automated, and automated complete differential WBC count (CBC)
HCPCS 85027	Blood count; hemogram and platelet count, automated

19. Indices are measurements and ratios calculated from the results of hematology tests. The indices included in "hematology, automated" profiles above are usually a group of three red cell indices used for screening hematological abnormalities. The MCV (mean corpuscular volume) is the size (volume) of the average red cell. The MCH (mean corpuscular hemoglobin) is the weight of hemoglobin in the average red cell. The MCHC (mean corpuscular hemoglobin concentration) is the amount of hemoglobin present in the average red cell as compared to its size. The RBC indices are a guide to the choice of more specific measurements. See Laboratory

Test Handbook, D.S. Jacobs et al.,, Lexi-Comp Inc., 4th edition, page 344.

20. In addition to the standard indices, there are "additional" indices, the performance and subsequent billing of which is the subject of this complaint. The respective HCPCS codes are described in the CPT Code book as follows:

HCPCS 85029 Additional automated hemogram indices (eg. Red cell distribution width (RDW), mean platelet volume (MPV), red blood cell histogram, platelet histogram, white blood cell histogram); one to three indices

HCPCS 85030 four or more indices

21. The Medicare guidelines state that services that are not reasonable and necessary for the diagnosis or treatment of illness or injury are not covered. In order for the tests to be reimbursable by Medicare for services, including outpatient laboratory diagnostic tests, the tests must be medically necessary and the charges reasonable. 42 U.S.C. § 1395y(a)(1)(A) clearly states that medically unnecessary services are not reimbursable, and 42 C.F.R. § 411.406 requires that providers comply with the rules and regulations. The primary responsibility for implementing the medical-necessity rule rests with the providers. Section 1156 of the Social Security Act instructs providers that "it shall be the obligation of any [provider] ... to assure" that services or items ordered or provided, will be supported by evidence of medical necessity and quality presented in such form and fashion and at such time as may be reasonably required. 42 U.S.C. § 1320c-5.

22. Ernst & Young caused the nine hospitals to submit claims during the period from 1991 through 1997 to the Medicare Program, that reflected the billing of additional indices that were not medically necessary in accordance with Medicare guidelines. Plaintiff believes and

avers that Ernst & Young provided similar advice to and caused other hospitals to submit claims for additional indices which were not medically necessary.

The Ernst & Young Reviews

23. For the nine hospitals, Ernst & Young performed two types of reviews, which are described below. As a result of these reviews, Ernst & Young recommended to the hospitals that they bill or continue to bill separate charges for additional indices, 1) when the tests were performed automatically on the hematology equipment, 2) routinely when another complete blood count ("CBC") was ordered, and/or 3) without the requisite physician's order. At no time during these reviews did Ernst & Young advise the hospitals to stop billing the tests separately when they were not medically necessary.

Charge Description Master Reviews ("CDM" Review)

24. Ernst & Young performed CDM Reviews (also referred to as Operational Analysis or Pricing Reviews) and subsequently prepared reports for the following known hospital providers: William Wishard Memorial Hospital ("Wishard"), located in Indianapolis, Indiana; Logansport Memorial Hospital ("Logansport"), located in Logansport, Indiana; Depaul Medical Center, Bon Secours Health System ("Depaul"), located in Norfolk, Virgina; and Good Samaritan Regional Medical Center ("Good Samaritan"), located in Pottsville, Pennsylvania.

25. The procedures typically performed by Ernst & Young for the CDM Review included: assessing the accuracy of the HCPCS codes assigned to frequently performed procedures on the CDM, reviewing the charge structure, reviewing the UB-82 revenue code assignment for mapping to the HCPCs code assignment, interviewing personnel involved in the coding and billing process, and evaluating the reimbursement impact of suggested changes. One

objective was to review the accuracy of the CDM as it related to coding and charges, and to compare what is coded to what is actually performed. Ernst & Young also compared what is coded to what could be performed. For instance, if the hematology analyzer equipment was automatically generating additional indices, or was capable of automatically generating additional indices, Ernst & Young recommended specific changes or additions to the CDM, upon which the hospitals relied.

26. Ernst & Young did not take the steps necessary to describe the circumstances under which the additional indices could be billed, that is, when the tests to be performed were medically necessary. The Ernst & Young consultants were hired as the experts, who knew how a typical hospital's billing system worked and who knew the consequences of their coding advice.

27. Ernst & Young's recommendations to the four hospitals for which it performed CDM Reviews were targeted towards "optimization of outpatient reimbursement," by adding a new charge for additional indices that would be "linked" or automatically generated whenever a blood cell profile was billed; the additional reimbursement would only be sought from "fee schedule-based payors," primarily Medicare, but not from charge-based payors, most frequently private insurers. Through Ernst & Young's recommendations, the hospitals would economically benefit from the claims submitted to Medicare.

Allegations Relating to Depaul

28. Ernst & Young conducted an Operational Pricing Review for Depaul, resulting in a Report dated October 1992. Ernst & Young found that whenever Depaul performed a CBC, it was using an instrument that always performed additional indices, and these indices were reported with each CBC. Without regard to whether the additional indices were medically

necessary each time the CBC was performed, Ernst & Young recommended that Depaul develop a charge for additional indices, and charge Medicare for additional indices whenever a CBC was ordered. Ernst & Young further advised Depaul to reduce the charge for the corresponding CBC by the amount assigned to the additional indices "in order to maintain the total charge." In doing so, they assured the hospital that "total outpatient reimbursement from Medicare will increase" by following their advice, but that no other customer would pay more.

29. In Depaul's report, Ernst & Young estimated that an annual volume of 5,847 outpatient Medicare CBCs were performed, and the lab would therefore receive an additional $27,000 in annual Medicare reimbursement "from additional hemogram indices charged in association with the CBC." At the time of this recommendation, Ernst & Young knew that each time Depaul performed a CBC, additional indices would also be billed to Medicare for reimbursement, regardless of whether the tests were requested by or on behalf of a physician, or were medically necessary.

30. During the Metzinger investigation, which is described below, the United States became aware in November 1995 in the findings of another independent accounting firm that Ernst & Young had given advice to Depaul to separately bill for additional indices. The officers of the United States charged with the responsibility to act under the circumstances did not have, and in the exercise of reasonable diligence could not have had knowledge of the facts that form the basis of this claim prior to November 1995.

31. Depaul did begin billing for additional indices that were not medically necessary, pursuant to Ernst & Young's recommendation. The submission of claims with HCPCS code 85029 occurred approximately 21,800 times during the period from 1993 through 1995, and

caused Depaul to be overpaid by Medicare by approximately $113,000.

Allegations Relating to Good Samaritan

32. Ernst & Young conducted a Charge Master and CPT Coding Review for Good Samaritan, resulting in a report dated April 1994. In Attachment A-1 of the Report, it recommended that Good Samaritan add additional automated indices to its CDM, and that the additional automated indices should be "charged with the CBC" each time a CBC was performed. The recommendation of charging for additional services, each time the CBC was charged, was made without any regard to whether these procedures were medically necessary each time they would be charged. Ernst & Young estimated the annual Medicare outpatient volume for CBCs to be over 12,000 and the additional annual Medicare reimbursement to be $90,651.

33. The officers of the United States charged with the responsibility to act under the circumstances did not have, and in the exercise of reasonable diligence could not have had knowledge of the facts that form the basis of this claim for billing by Good Samaritan prior to September 1999.

34. Good Samaritan did begin billing for additional indices tests that were not medically necessary, pursuant to E&Y's recommendation. The submission of claims with HCPCS code 85029 occurred approximately 29,000 times during the period from 1994 through 1996, and caused Good Samaritan to be overpaid by Medicare by approximately $200,000.

Allegations Relating to Logansport

35. Ernst & Young conducted a Charge Description Master Review for Logansport, resulting in a report dated June 14, 1993. On page 3 of the report, Ernst & Young specifically

identified HCPCS code changes, CDM refinements and operational enhancements "targeted toward the optimization of outpatient reimbursement." Ernst & Young recommended a separate code for additional indices, RDW and MPV, because they are performed and reported routinely on the Hospital's hematology analyzer and "are not considered routine indices." Implementation of this recommendation would require the capability to link charge items in the billing system so that the additional indices would be transmitted to the bill when an "initial trigger" procedure, or CBC code 85025, was billed. Without regard to whether the tests were medically necessary each time they were performed, Ernst & Young on Attachment C of the report advised the Hospital to bill for additional indices separately, or HCPCS code 85029 when a CBC was ordered.

36. In Attachment C of the Logansport report, Ernst & Young estimated that an annual volume of 3,696 outpatient Medicare CBCs were performed, and the lab would therefore receive an additional $15,634 in annual Medicare reimbursement from additional hemogram indices linked to the CBC. In its recommendation to the hospital, Ernst & Young stated that the linking of the charge items would result "in added reimbursement for the additional procedure code from the fee schedule-based payors" (i.e. Medicare) and not from the charge-based payors.

37. The officers of the United States charged with the responsibility to act under the circumstances did not have, and in the exercise of reasonable diligence could not have had knowledge of the facts that form the basis of this claim prior to July 26, 1999, when they were advised that Ernst &Young had recommended to Logansport in 1993 that they begin billing for additional indices.

38. Logansport did begin billing for additional indices tests that were not medically necessary, pursuant to Ernst &Young's recommendation. The submission of claims with

HCPCS code 85029 to the Medicare program occurred approximately 12,369 times during the period from 1993 through 1996 and caused Logansport to be overpaid by Medicare by approximately $53,000.

Allegations Relating to Wishard

39. Ernst & Young conducted a Charge Description Master Review for Wishard, resulting in a report dated March 27, 1991. On page 2 of the cover letter, Ernst & Young specifically identified HCPCS code changes, CDM refinements and operational enhancements "targeted toward the optimization of outpatient reimbursement." Ernst & Young recommended to the Hospital to start routinely billing for additional indices whenever a blood cell profile was performed. The report specifically stated that a new automated additional indices code should be "linked" with the blood cell profile code "so that charges for both procedures are "exploded" when only the blood profile is ordered. Without regard to whether the tests were medically necessary each time they were performed, Ernst & Young on Attachment A of the report advised the Hospital to add a laboratory procedure, additional indices, and to bill for the procedure separately with HCPCS code 85029.

40. Ernst & Young's advice to Wishard was not limited to telling the hospital to start billing routinely for additional indices. They advised the hospital to start routinely reporting the additional indices which the physicians did not order, and did not need, so they could then charge for the additional indices.

41. In Attachment A of the Wishard report, Ernst & Young estimated that the annual Medicare/Medicaid outpatient volume for blood cell profiles in 1991 was 97,890, and the lab would therefore receive an additional reimbursement of $384,708 for the additional charge for

additional indices in 1991. On page 1 of its recommendations to the hospital, Ernst & Young further advised the hospital to reduce the charge for the blood cell profile while at the same time adding the charge for the additional indices. With the addition of HCPCs code 85029, Ernst & Young told the Hospital it would realize an increase in net revenue for every blood cell profile performed on Medicare/Medicaid patients. On the other hand it noted that reducing the charge for the blood cell profile would prevent any visible impact on payors other than Medicare or Medicaid.

42. The officers of the United States charged with the responsibility to act under the circumstances did not have, and in the exercise of reasonable diligence could not have had knowledge of the facts that form the basis of this claim prior to July 26, 1999, when they were advised that Ernst &Young had recommended to Wishard in 1991 that they begin billing for additional indices .

43. Wishard did begin billing for additional indices tests that were not medically necessary, pursuant to Ernst &Young's recommendation. The submission of claims with HCPCS code 85029 to the Medicare Program occurred approximately 27,750 times during the period from 1991 through 1996, and caused Wishard to be overpaid by Medicare by approximately $115,000.

Independent Reviews for Metzinger Investigation

44. William Ritter and Harry Metzinger ("Metzinger Associates") were billing consultants to hospitals. During the period 1988 through 1993, Ritter traveled throughout the northeast and midwestern states of the United States, soliciting clients for their partnership, Metzinger Associates. The agreement Metzinger Associates offered hospitals was relatively

straightforward; Ritter would, after review of hospital laboratory billing policies, provide advice on improving billing recoveries. For the first year after his advice was implemented, Metzinger would receive 25% or more of reimbursement of the additional payments to the hospital resulting from his advice.

45. Over 200 hospitals entered into agreements with Metzinger Associates including the following five hospitals, which were also consulting clients of Ernst & Young, at least during the second half of 1995: Community Hospital of Anderson and Madison County ("Community - Anderson") located in Indianapolis, Indiana; Conemaugh Medical Center ("Conemaugh"), located in Johnstown, Pennsylvania; Pocono Medical Center ("Pocono"), located in East Stroudsburg, Pennsylvania; Kane Community Hospital ("Kane"), located in Kane, Pennsylvania, and Norwalk Hospital ("Norwalk"), located in Norwalk, Connecticut.

46. The conduct of hospitals who had signed these agreements varied widely; some refused to implement any Ritter advice, some implemented some suggestions but not others, some implemented virtually all his suggestions. Certain of Ritter's advice was perfectly legal. The validity of his advice depended upon the systems, processes and laboratory techniques actually used by the hospital. Some of the advice was questionable, or appropriate in some jurisdictions but not others; some of his advice was improper, and if implemented, would result in improper payments to the hospital.

47. During the first six months of 1995, a consultant retained by the United States, as well as auditors from the Department of Health and Human Services, analyzed each area of laboratory coding advice given by Ritter to determine whether it was consistent with governing rules. This included consideration of the relevant history of the American Medical Association's

("AMA") CPT committee and written guidance made by Medicare carriers and intermediaries.

48. During the first six months of 1995, the United States also obtained laboratory billing data from the Department of Health and Human Services' Common Working File ("CWF") showing specific laboratory code billing for each hospital. This billing data was compared to the date of Ritter's visits and provision of coding advice to determine whether billing practice changes might have occurred after Ritter had provided advice.

49. In the summer of 1995, the United States and the Office of Inspector General ("OIG") provided to each of the Metzinger client hospitals a summary of some of the areas of advice provided by Ritter about which the United States had concerns, together with a summary of that hospital's billings for selected CPT codes by year. The United States also scheduled a meeting to discuss its planned approach to determining whether any potentially inappropriate billings might have occurred. That meeting occurred on July 6, 1995, in Philadelphia, and was attended by counsel and/or the professional advisors for a variety of hospitals. For the hospitals named in paragraph 45 above, Ernst & Young attended this meeting. Each hospital was asked to conduct a review of its laboratory billing in light of the concerns raised by United States, to follow a sample work plan developed by the United States, and to provide a report by an outside, professional advisor concerning those concerns. In the alternative, the United States explained that the Inspector General would arrange such a review using the Inspector General's personnel and inspection authority.

50. Ernst & Young submitted reports to the United States dated August 30, 1995, on behalf of its clients: Community - Anderson, Conemaugh, Kane and Norwalk. Pocono's initial report was dated October 12, 1995. Each Ernst & Young report purported to respond to the

request for a review by an outside professional advisor. Each report initially submitted fell far short of the request by the United States. Each report purported to be in compliance with the requests of the United States. These reports were created and submitted with the effect of misleading the United States as to the extent of improper billing, and the involvement of the hospital in improper billing. Plaintiff believes and avers that with respect to these hospitals, Ernst & Young knew or recklessly disregarded the fact that the reports would mislead the United States as to the extent of the improper billing. Each report was submitted in support of a false claim, and to reduce the hospital's liability for false claims.

51. Notwithstanding specific notice that the United States believed that billing for additional indices was improper, unless there existed both medical necessity and physician order for each set of tests, Community - Anderson, Conemaugh and Pocono were billing for additional indices while Ernst & Young was performing its independent reviews. These hospitals continued to bill for additional indices even after the reviews had been completed and Ernst & Young submitted its initial reports. Both Norwalk and Kane began billing for additional indices within three months of when Ernst & Young submitted its reports to the United States.

52. In July 1997, the United States received from the USAO Region 1 contractor, Mayer, Hoffman & McCann ("Mayer") diskettes that identified potential Medicare overpayments to some Pennsylvania and Indiana hospitals for outpatient laboratory claims with dates of service in 1994 and 1995. The data identified by HHS Audit in Region 1 reflected the billing of certain hematology codes, including additional indices, as part of a national project often referred to as "Laboratory Unbundling." The listing of claims reflected the hospitals's billing patterns but did not provide confirmation on whether the tests were actually performed, or performed in

accordance with a physician's request.

Allegations Relating to Community - Anderson

53. During Ernst & Young's review for Community - Anderson, there were no physician requests available for the test year, 1991 and additional indices were not stated on Community-Anderson's lab requisition form. Yet in their report dated August 30, 1995, Ernst &Young stated that the hospital should be billing HCPCS code 85029 instead of HCPCS code 85030. There were no physician requests available to test whether the additional indices charged on the claims submitted were medically necessary each time the tests were performed.

54. Ernst & Young never recommended to Community - Anderson that it pay back to the Medicare Trust Fund the improper billings for additional indices when the tests were not medically necessary, for the years 1991 through 1995. Instead, it recommended that the hospital pay back the difference between billing for HCPCS code 85029 and HCPCS code 85030, which allowed the hospital to retain funds to which it was not entitled. Further, the advice of Ernst & Young caused the hospital to continue to submit false claims through 1997 without regard to whether the tests were medically necessary.

55. For the period from 1991 through 1997, Community - Anderson submitted approximately 38,200 claims with additional indices to the Medicare Trust Fund for payment, and Community - Anderson as a result was overpaid by Medicare by approximately $255,000.

Allegations Relating to Conemaugh

56. Ernst & Young submitted an initial report to the United States on or about August 30, 1995 on behalf of Conemaugh. This report intentionally failed to include any information about the hospital's billing for additional indices, when Ernst & Young knew at that time that the

hospital was doing so. Ernst & Young's workpapers show that additional indices were included in the data collection and claims testing phases of Ernst & Young's review.

57. The minutes from Conemaugh's Therapeutics Committee (October 25, 1993) show that Ernst & Young prepared a list of panels and tests (including additional indices) that "would be approved by Medicare," and should be approved by Conemaugh's Executive Committee. The code for additional indices was added to the CDM in 1993. The hospital began billing for additional indices in 1993 and continued to bill through 1996.

58. The officers of the United States charged with the responsibility to act under the circumstances did not have, and in the exercise of reasonable diligence could not have had knowledge of the facts that form the basis of this claim prior to July 1997, when they were in receipt of the diskette of claims from Mayer.

59. In response to the United States investigation and inquiries, Cap Gemini in 2000 submitted a second report on behalf of Conemaugh to the United States which did include the submission of approximately 34,000 claims by Conemaugh with additional indices for the years 1993 through 1996, for which the hospital was overpaid by Medicare by approximately $98,000.

Allegations Relating to Pocono

60. Pocono was billing for HCPCS code 85029 since 1994 but it was never mentioned in Ernst & Young's initial report dated October 12, 1995. This report intentionally failed to include any information about the hospital's routine billing for additional indices when Ernst & Young knew at that time that the hospital was doing so.

61. Ernst & Young's workpapers confirmed that in response to the United States investigation and inquiries regarding additional billing practices, Pocono prepared a letter to its

legal counsel dated May 29, 1996. The follow-up items were addressed by Pocono with the assistance of Ernst & Young. The letter stated that Pocono began billing for additional indices in 1994 because they were routinely performed as a part of their CBC. This letter was not provided to the United States until 2002.

62. Even though Ernst & Young knew that Pocono was billing for additional indices that were performed routinely, Ernst & Young submitted a second report dated June 14, 1996 to the United States, which intentionally omitted any mention of the improper billing of additional indices.

63. The officers of the United States charged with the responsibility to act under the circumstances did not have, and in the exercise of reasonable diligence could not have had knowledge of the facts that form the basis of this claim prior to July 1996 when they were in receipt of a computer generated printout from DHHS in Region 3, which contained a sample of claims with dates of service for 1994 only. The billing of some of the additional indices during the year 1994 was included in the settlement agreement with Pocono.

64. In a letter to the United States dated August 6, 1997 counsel for Pocono acknowledged that Ernst & Young discovered during a mandated corporate compliance review that Pocono was still billing for additional indices during the years 1995 and 1996.

65. For the period from 1994 through 1996, Pocono submitted approximately 27,600 claims with additional indices to the Medicare Trust Fund for payment, and Pocono, as a result was overpaid by Medicare by approximately $189,000.

Allegations Relating to Norwalk

66. During Ernst & Young's review of Norwalk's outpatient laboratory billings, Ernst &

Young reviewed Norwalk's CDMs for the years 1987 through 1994 and learned that the hospital was not billing for additional indices, even though the new hematology equipment purchased in 1990 was capable of performing a "hematology profile" that included additional indices (i.e. RDW and MPV.) The lab results that Ernst & Young looked at during their claims testing showed that for dates of services beginning during the latter part of 1990, additional indices were in fact added to the Norwalk's hematology profile. Ernst & Young's workpapers further confirmed that on February 15, 1990, Norwalk's department of pathology submitted a request specifically to add a new hematology test to the hematology Coulter equipment.

67. Ernst & Young submitted an initial report to the United States on behalf of Norwalk, in the Metzinger investigation. Ernst & Young's report dated August 30, 1995 to the United States did not address additional indices, even though Ernst & Young looked at "PMS billing transactions" dated August 4, 1995 which reflected the billing of HCPCS code 85029. It reported on page 9 that new hematology equipment was installed in June 1990, which reported an automated five part differential "whereby all CBC and CBC with differential orders generated an automated cell count with automated differential." Not only were the tests being performed routinely along with the CBC, but the physicians did not have the option to select additional indices because they were not listed on the lab requisition forms. Ernst & Young advised Norwalk to start billing for additional indices. The Hospital began billing for HCPCS code 85029, for dates of services rendered on or about May 1995, and continued to bill for these tests through 1996.

68. The officers of the United States charged with the responsibility to act under the circumstances did not have, and in the exercise of reasonable diligence could not have had

knowledge of the facts that form the basis of this claim prior to July 1997, when they were in receipt of the diskette of claims from Mayer with dates of services for the year 1995.

69. For the period from 1995 through 1996, Norwalk submitted approximately 11,275 claims with additional indices to the Medicare Trust Fund for payment, and Norwalk, as a result was overpaid by Medicare by approximately $76,000.

Allegations Relating to Kane

70. In 1989, Metzinger Associates did recommend to Kane that it begin billing for HCPCS code 85029, but the code was not implemented by Kane at that time. The CDM dated July 20, 1995 in Ernst & Young's workpapers did not reflect HCPCS code 85029 for additional indices and the sample inquiry screen for order entry, as of July 1995, did not list the additional indices. During Ernst & Young's review in 1995, however, its workpapers show that new hematology equipment was purchased by Kane on March 30, 1994 and that by July 1995 the lab results reflected that additional indices were automatically being performed. Ernst & Young also noted that the lab requisition forms in Ernst & Young's workpapers did not contain additional indices as a selection option for physicians.

71. Ernst & Young's report dated August 30, 1995 prepared for Kane did not mention anything about additional indices. It did acknowledge that "a new hematology analyzer, capable of performing a 3-part automated differential was not purchased until 1994." The hospital began billing for HCPCS code 85029, for dates of services rendered on or about September 1995, and continued to bill for these tests through 1996.

72. The officers of the United States charged with the responsibility to act under the circumstances did not have, and in the exercise of reasonable diligence could not have had

knowledge of the facts that form the basis of this claim prior to July 1997 when they were in receipt of the diskette of claims from Mayer with dates of services for the year 1995.

73. For the period from 1995 through 1996, Kane submitted approximately 2,190 claims with additional indices to the Medicare Trust Fund for payment, and Kane, as a result was overpaid by Medicare by more than $14,500.

74. Attached as Exhibit 1 to this complaint is a sample of forty-five claims, representing the improper submission of claims by nine of the hospitals named above, which contained charges for additional indices tests performed during the relevant time period, as described above in the paragraphs 24 through 73. The claims are listed with patient number,[2] DCN Claim Number, Dates of Service, and relevant HCPCS codes.

75. Ernst & Young knowingly caused the submission of false claims for medically unnecessary services.

76. Ernst & Young knowingly made or used, or caused to be made or used, false or fraudulent documents in support of false claims.

77. Each of the claims for payment is a false claim for payment from federal funds.

78. As a result of Ernst & Young causing the submission of over two hundred thousand false claims, Medicare, through the fiscal intermediaries processing the claims of each of the nine hospitals addressed above, paid federal funds to the hospitals to which they were not entitled.

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[2] In accordance with federal regulations governing patient privacy, the United States has redacted each beneficiary's Medicare HIC number from this Exhibit and assigned a simple numerical reference 1 - 45 for each Medicare beneficiary in the sample.

Defendant Kept Itself Deliberately Ignorant

79. Ernst & Young, during its reviews, failed to effectively follow through with its clients to ensure compliance with Medicare guidelines. Ernst & Young failed to explain to the hospitals when the advice for billing of the additional charges would be inappropriate. Ernst & Young failed to explain to the hospitals why the advice for billing of the additional charges would be appropriate. Ernst & Young failed to undertake appropriate sampling, or review of individual outpatient laboratory claims for additional indices, between 1991 and 1997. And, Ernst & Young failed to undertake any effective and/or appropriate inquiry into the accuracy of its advice regarding the claims submission process and program. The failure to undertake any of these actions allowed Ernst & Young to keep itself deliberately ignorant of the truth or falsity of its advice regarding the billing for additional indices to Medicare. The hospitals relied upon the recommendations made by Ernst & Young. The failure to undertake any of these actions caused the hospitals to submit false claims to the Medicare Program.

80. In response to the Metzinger reviews beginning in 1995, Ernst & Young did not fully disclose in its reports the improper billing related to additional indices. Ernst & Young failed to review for medical necessity, when it was clear that physician requests were not available. Ernst & Young failed to address additional indices when there were volume statistics which indicated the billing of the HCPCS codes, either 85029 or 85030. Ernst & Young failed to address additional indices when they had been recommended by Metzinger Associates as directed in the United States workplan (attached to the letters sent to the Hospitals in June or July of 1995). Ernst & Young failed to disclose the billing of additional indices that was implemented either just prior or just after the independent review. The failure to undertake any of these actions allowed

Ernst & Young to keep itself deliberately ignorant of the truth or falsity of the claims being submitted with additional indices to Medicare. It was Ernst & Young's responsibility as the independent reviewer to be alert to fraud and abuse not to ignore it.

81. During the period from 1991 through 1997, Ernst & Young did not have in place an audit protocol which encompassed all facets of a proper and thorough CDM or outpatient laboratory billing review. The protocol should have included, among other things, procedures to ensure billing accuracy and compliance with Medicare, Medicaid and other federally funded health care regulations, guidelines and requirements imposed on clinical laboratories.

82. The United States, through the United States Attorney's Office, Eastern District of Pennsylvania ("USAO") notified Ernst & Young in a letter dated May 25, 2001 that it was conducting an on-going investigation of Medicare claims that were submitted for certain outpatient clinical laboratory services upon the advice of Ernst & Young.

83. The United States and Ernst & Young subsequently entered into a tolling agreement that tolled the Statute of Limitations set forth in the False Claims Act, 31 U.S.C. § 3729 et seq, or in 28 U.S.C. § 2416 - 2416 from July 3, 2001. That tolling agreement remains in effect until January 5, 2004.

84. Facts material to the United States' right of action for unjust enrichment and payment under mistake of fact against Ernst & Young were not known, and reasonably could not have been known by an official of the United States charged with the responsibility to act under the circumstances, at the earliest, prior to November 3, 1995. Thus, all of the unjust enrichment and payment under mistake of fact claims asserted herein are timely.

COUNT I
FALSE CLAIMS ACT 31 U.S.C. §3729 (a) (1)

85. The United States re-alleges paragraphs 1 through 84 above as if fully set forth herein.

86. Ernst & Young knowingly caused the submission of false or fraudulent claims to Medicare for payment using federal funds between January 1, 1991 and December 31, 1997.

87. Each of the claims submitted because of the advice given by Ernst & Young, is a separate false claim against federal funds.

COUNT II
FALSE CLAIMS ACT 31 U.S.C. §3729 (a) (2)

88. The United States re-alleges paragraphs 1 through 87 above as if fully set forth herein.

89. Ernst & Young knowingly made or used, or caused to be made or used, false or fraudulent documents in support of false claims.

90. Each of the claims submitted because of the advice given by Ernst & Young, is a separate false claim against federal funds.

COUNT III
UNJUST ENRICHMENT

91. The United States re-alleges paragraphs 1 through 90 above as if fully set forth herein.

92. The hospitals that relied upon the advice of Ernst & Young have been unjustly enriched by its course of conduct as alleged in this complaint between January 1, 1991 and December 31, 1997 to the detriment of the United States.

COUNT IV
PAYMENT BY A MISTAKE OF FACT

93. The United States re-alleges paragraphs 1 through 92 above as if fully set forth herein.

94. As a result of Ernst & Young's conduct, the hospitals were paid federal funds from the United States Treasury that were not properly payable.

95. At the time that such payments were made, the United States was not aware of Ernst & Young's wrongful conduct. Had the United States known that the hospitals to whom Ernst & Young had given this advice were not entitled to receive payments, it would not have approved payment of such funds.

96. The United States is entitled to recover those funds paid by mistake on account of Ernst & Young's conduct between January 1, 1991 and December 31, 1997.

WHEREFORE, the United States respectfully requests judgment against the Defendant as follows:

A. On Count I for judgment against the Defendants and in favor of the United States for treble its damages, and for a civil penalty for each false claim submitted to Medicare and for each false record or statement made, as allowed by law.

B. On Counts II & III for judgment against the Defendants and in favor of the United States for its damages, prejudgment and post judgment interest, costs and other proper relief.

JURY DEMAND

The United States hereby demands a trial by jury as to all issues so triable.

Respectfully submitted,

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Dated: January 5, 2004